NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THOMAS BIONDOLILLO, individually and on behalf of all others similarly situated,

Plaintiff,

v.

ROCHE HOLDING AG, SEVERIN SCHWAN, ALAN HIPPE, DANIEL O'DAY, and GOTTLIEB A. KELLER,

Defendants.

Civ. No. 17-4056

OPINION

THOMPSON, U.S.D.J.

INTRODUCTION

This matter comes before the Court upon the Motion to Dismiss filed by Defendants Roche Holding AG ("Roche"), Severin Schwan, Alan Hippe, Daniel O'Day, and Gottlieb A. Keller (collectively, "Defendants"). (ECF No. 40.) Plaintiff Thomas Biondolillo, on behalf of a putative class, opposes and, in the alternative, seeks leave to amend the operative Complaint. (ECF No. 42.) The Court has decided the Motion on the written submissions of the parties, pursuant to Local Rule 78.1(b). For the reasons stated herein, the Motion to Dismiss is granted, and Plaintiff is granted leave to amend the operative Complaint.

BACKGROUND

In this securities case, the Court previously granted a Motion to Dismiss the First Amended Complaint. (Op., ECF No. 35; Order, ECF No. 36.) Plaintiff then filed a Second Amended Complaint ("SAC") (ECF No. 37), and the present Motion seeks its dismissal as well.

Roche is a biotechnology company whose primary business is in cancer treatments. (*Id.* ¶

41.) Defendants Schwan, Hippe, O'Day, and Keller (collectively,"Individual Defendants") held leadership roles at Defendant Roche and served on its Corporate Executive Committee. (*Id.* ¶¶ 28–31.) This case concerns allegedly false and misleading statements made by Defendants concerning the APHINITY Phase III Study ("APHINITY"), which tested the effects of Herceptin with another drug, Perjeta. (*Id.* ¶¶ 61, 65.) Herceptin is Defendant Roche's second-highest-grossing product, but its continuing sales are threatened by competition from biosimilars (drugs with similar active properties). (*Id.* ¶¶ 3, 51.) If APHINITY were to find that a combination of Perjeta, Herceptin, and chemotherapy (the "Perjeta-based regimen") improved patient outcomes in the adjuvant (post-surgery) setting, "not only would an increase in revenues from Perjeta offset revenue losses from Herceptin biosimilar competition, the sales life of Herceptin would also be extended, protecting billions in Roche revenue." (*Id.* ¶ 64.)

The full results of APHINITY would be received by Defendant Roche in March 2017 and released to the public in June 2017. (*Id.* ¶ 68.) After Defendant Roche had received the full APHINITY results but before those results were released, Defendants made several statements concerning APHINITY's "top-line" results that are alleged to be false and misleading.

Many of these statements were analyzed in the Court's previous Motion to Dismiss Opinion. (*See* Op. at 3–4, 7–10.) On March 2, 2017, Defendant Roche issued a press release announcing APHINITY's "positive results," claiming that it found a "statistically significant improvement in invasive disease-free survival," and "met its primary endpoint," and stating that "[t]he safety profile of the Perjeta-based regimen was consistent with that seen in previous studies," and that "no new safety signals were identified." (Op. at 3; SAC ¶ 80.) Additionally, Defendant O'Day stated in an April 27, 2017 conference call that the APHINITY results were "clinically meaningful" and "terrific news for patients," and that the Perjeta-based regimen can

"improve the standard of care systematically" and provides "a curative setting . . . with early breast cancer." (Op. at 3–4; SAC ¶¶ 90–92.) In its Opinion, the Court found that these statements were not materially misleading. (Op. at 8–10.) The Court also found that the First Amended Complaint failed to adequately plead scienter for Defendants Schwan, Hippe, and Keller. (*Id.* at 11–12.)

The Second Amended Complaint adds two new sets of facts allegedly demonstrating that Defendants made false and misleading statements. (*See* Redlined SAC, ECF No. 52 (showing new material in the SAC).)[1] First, the March 2, 2017 press release stated that the Breast International Group ("BIG"), one of the study collaborators, "facilitates breast cancer research at an international level, by stimulating cooperation between its members and other academic networks, and collaborating with, but working independently from, the pharmaceutical industry." (SAC ¶ 67.) It was later revealed that Defendant Roche had paid Dr. Jose Baselga—who was one of the study collaborators, a listed study author, and an executive member of BIG—over $3 million in consulting fees and for a stake in a company Defendant Roche acquired. (*Id.* ¶¶ 66–67, 134–35.) Plaintiff argues that these revelations show that the press release's claim of BIG's independence was misleading. (*Id.* ¶ 141.)

Second, both Defendant Schwan and Defendant O'Day made comments concerning the standard of care. In an April 27, 2017 interview with Bloomberg, Defendant Schwan said, "[t]he answer is not that you defend your old franchises. The answer is that you move the standard of care." (*Id.* ¶ 56 (brackets in SAC).) On the same day, Defendant O'Day stated in a Sales and Revenue Call, "And with the APHINITY trial, you see now that chart nicely filled out, essentially with one medicine in combination has been able to improve the standard of care

[1] It also adds facts to demonstrate scienter. (SAC ¶¶ 110, 144, 151.)

systematically across metastatic, neoadjuvant and now adjuvant." (*Id.* ¶ 90.) He also said, "We've now got Perjeta showing significant increase in the standard of care and all the indications at a 2x price." (*Id.* ¶ 92.)

According to the Second Amended Complaint, "standard of care" means "treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard medical care, and standard therapy." (*Id.* ¶ 58.) In this context, "mov[ing] the standard of care" would mean "the Herceptin/Perjeta combination becom[ing] the new, accepted and widely used treatment for HER2-positive early breast cancer in the entire applicable patient population." (*Id.* ¶ 59.) Plaintiff argues that Defendants' statements concerning the standard of care were misleading because they suggested that the new regimen would be widely used for the entire patient population, while the APHINITY results supported such treatment only for one subgroup of patients. (*Id.* ¶ 144.) Plaintiff also avers misrepresentation because

> sales of Perjeta in the adjuvant setting did not increase, and revenues from a Herceptin/Perjeta combination did not offset lost revenues from Herceptin due to biosimilar competition in Europe, where a Herceptin biosimilar was already on the market. In reporting on Q3 2017 a SeekingAlpha report stated: "HER2 franchise sales (Herceptin, Perjeta and Kadycycla) were CHF 1.4% lower than consensus, driven by a weak performance of Herceptin in Europe and Perjeta. It's worth noting that there hasn't been any acceleration of the growth trajectory for Perjeta after the disappointing results from the Phase III trial APHINITY, assessing the benefits of adding Perjeta to Herceptin in adjuvant HER2-positive breast cancer."

(*Id.* ¶ 132 (emphasis removed).)

Plaintiff filed the Second Amended Complaint on October 15, 2018, alleging that all Defendants violated Section 10(b) of the Securities Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5, 17 C.F.R. § 240.10b-5 (*id.* ¶¶ 161–70); and that Individual Defendants violated Sections 20(a) and 20A of the Securities Exchange Act, 15 U.S.C. §§ 78t(a), 78t-1 (*id.* ¶¶ 171–85).

Following the timeline set by a Stipulation and Consent Order (ECF No. 39), Defendants moved to dismiss on December 21, 2018 (ECF No. 40), Plaintiff opposed on February 18, 2019 (ECF No. 42), and Defendants replied on March 20, 2019 (ECF No. 47).[2] The Motion is presently before the Court.

LEGAL STANDARD

A motion to dismiss under Rule 12(b)(6) of the Federal Rule of Civil Procedure tests the sufficiency of a complaint. *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993). The defendant bears the burden of showing that no claim has been presented. *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). When considering a Rule 12(b)(6) motion, a district court should conduct a three-part analysis. *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). "First, the court must 'take note of the elements a plaintiff must plead to state a claim.'" *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009)). Second, the court must "review[] the complaint to strike conclusory allegations." *Id.*; *see also Iqbal*, 556 U.S. at 679. Finally, the court must assume the veracity of all well-pleaded factual allegations and "determine whether the facts are sufficient to show that plaintiff has a 'plausible claim for relief.'" *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (quoting *Iqbal*, 556 U.S. at 679); *see also Malleus*, 641 F.3d at 563. If the complaint does not demonstrate more than a "mere possibility of misconduct," it must be dismissed. *See Gelman v. State Farm Mut. Auto. Ins. Co.*, 583 F.3d 187, 190 (3d Cir. 2009) (quoting *Iqbal*, 556 U.S. at 679).

Additionally, in a securities case, the Private Securities Litigation Reform Act ("PSLRA") imposes a more demanding pleading standard. To allege a false or misleading

[2] Plaintiff also moves to strike four exhibits attached to the Motion to Dismiss. (ECF No. 44.) The Court has not considered these exhibits in deciding the Motion to Dismiss and will dismiss the Motion to Strike as moot.

statement or omission, the complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). This pleading standard is effectively the same as the one provided by Rule 9(b) of the Federal Rules of Civil Procedure, which requires that the complaint "state with particularity the circumstances constituting fraud." *Inst. Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 253 (3d Cir. 2009).

Although a district court generally must confine its review on a Rule 12(b)(6) motion to the pleadings, *see* Fed. R. Civ. P. 12(d), "a court may consider certain narrowly defined types of material" beyond the pleadings, *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999), including matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, and items appearing in the record of the case. *Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006) (internal citation omitted).

DISCUSSION

I. The Second Amended Complaint Fails to State a Claim Under Section 10(b)

To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must show "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37–38 (2011) (citing *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008)); *accord City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014). The Court has already held that allegations contained in the First Amended Complaint failed to demonstrate material misrepresentation, the first element. (Op. at

7–10.)[3] And, as explained in further detail below, neither of the two new sets of facts alleged in the Second Amended Complaint demonstrate that Defendants made material misrepresentations. The operative Complaint therefore fails to state a claim upon which relief can be granted.

A. *Statement About BIG's Independence*

The March 2, 2017 press release stated that BIG "facilitates breast cancer research . . . by . . . collaborating with, but working independently from, the pharmaceutical industry." (SAC ¶ 67.) In determining whether a statement is false or misleading, the Court must give the statement a "full reading," *Pfizer*, 754 F.3d at 169, and a full reading of this statement shows that it is incoherent. To collaborate is "to work jointly with others." Merriam-Webster's Online Dictionary, https://www.merriam-webster.com/dictionary/collaborate (last visited Mar. 29, 2018). So the press release contradicts itself by claiming that BIG is "collaborating with" the pharmaceutical industry while also "working independently from" it. The statement is oxymoronic, not misleading.[4]

B. *Statements About the Standard of Care*

Defendants said, at various times, "you move the standard of care" (SAC ¶ 56), "one medicine in combination has been able to improve the standard of care systematically across metastatic, neoadjuvant and now adjuvant" (*id.* ¶ 90), and "[w]e've now got Perjeta showing significant increase in the standard of care" (*id.* ¶ 92). These statements are not false or misleading.

[3] All parties, in their respective briefs, appear to ask the Court to reconsider portions of its previous ruling. (Mot. at 33–36; Opp'n at 20–22.) The Court declines to do so.

[4] In his brief, Plaintiff argues that releasing the APHINITY results without disclosing the potential conflict of interest among Defendants, BIG, and Dr. Baselga is itself a material omission that makes statements about the study misleading. (Opp'n at 28–29.) The Court will not evaluate this argument because it is absent from the Second Amended Complaint, which is required to "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1).

First, it is important to note that none of these statements claimed that the Perjeta-based regimen *had become* or *would become* the standard of care; rather they claimed that it "improve[d]" and "significantly increase[d]" the standard of care. Thus, these statements do not suggest that the regimen was, or was bound to be, widely used by the entire patient population. Plaintiff's argument to that effect misses the mark.

Second, Defendant Schwan's statement—"The answer is that you move the standard of care."—is most sensibly read as a statement of the company's strategy, not as a comment on APHINITY results. There is no reason to believe that Defendant Schwan's statement misrepresented Defendant Roche's strategy.

Third, to the extent that the above statements are interpretations of the APHINITY results, the Court has already held that such statements are matters of opinion. (Op. at 10 (citing *Pfizer*, 754 F.3d at 170).) And, as before, Plaintiff has not shown that the declarants did not honestly believe what they were saying or that they lacked a reasonable basis for the statements.

Finally, no other facts have been presented to show that Defendants' statements about the standard of care were false or misleading. The Second Amended Complaint provides several facts to establish the falsity of these statements. (SAC ¶¶ 140, 144–46.) Several of these facts have been discussed in the Court's previous Opinion, and the Court incorporates its prior reasoning. (Op. at 9–10.) The Second Amended Complaint additionally purports that "sales of Perjeta in the adjuvant setting did not increase," but then quotes an article stating that sales *did* grow. (SAC ¶ 132 ("[T]here hasn't been any acceleration of the growth trajectory.").) Simply put, the Second Amended Complaint does not specify facts showing that the above statements were false or misleading. Accordingly, Defendants' Motion to Dismiss is granted.

II. The Second Amended Complaint Fails to State a Claim Under Sections 20(a) and 20A

Liability under Sections 20(a) and 20A are derivative of liability under Section 10(b). *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 247 (3d Cir. 2013) (quoting *Avaya*, 564 F.3d at 252); *Pfizer*, 754 F.3d at 175 (citing *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 541 (3d Cir. 1999)). Because the Second Amended Complaint fails to state a claim under Section 10(b), it also fails to state a claim under Sections 20(a) and 20A.

III. Leave to Amend is Granted

Rule 15(a)(2) of the Federal Rules of Civil Procedure allows amendment of the pleadings with the court's leave, which should be given freely. *Alvin v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000). Plaintiff is therefore granted leave to file an amended complaint pursuant to Local Civil Rule 15.1(b).

CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss is granted, and Plaintiff is granted leave to amend the Amended Complaint. An appropriate order will follow.

Date: 4/3/19

/s/ Anne E. Thompson
ANNE E. THOMPSON, U.S.D.J.